Blood-Stream Infection (CDC)

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To: Blood-Stream Infection (CDC)
Subject: Comments on IV Catheter 2009 Draft Guideline

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To the CDC Committee for the Guideline for the Prevention of Intravascular Catheter Related Infections

There are a number of discrepancies in the section on **Needleless Access Systems** (beginning line 1064) of the posted guideline that I have listed below and encourage the committee to consider prior to making final, substantive changes to the new guideline.

1. **"Wiping the access port" (lines 1074 – 1075)** is unclear. Most "wiping" is less than a one second swipe of an alcohol pledget. Yet the numerous "scrub-the-hub" case studies have shown that a sustained motion (often turning or described as "juicing an orange") is far more effective. What method is preferred and what should be the target duration of contact time t0 achieve optimum surface disinfection?

   Suggestions
   A. Identify best practice methods for cleaning/disinfecting the access surface.
   B. Give parameters for the amount of time necessary for achieving surface disinfection.

   Related to this, how is the tern "hub" being defined in this guideline? Does the term refer to the hub-like connection when any of the various needleless connectors are used or does the term refer to the hub of the IV catheter? Or both? This is particularly unclear in lines 1112-1114. The guideline is silent on the issue of cleaning/disinfecting the hub of the catheter. While it must be acknowledged that there is only a small amount of published literature on this topic, it is nonetheless relevant to the issue of maintaining a septic system, especially when devices must be changed.

   Suggestions
   A. Define what is meant by "hub" and, if necessary, differentiate it from the hub of the IV catheter.
   B. Describe best practice methods of cleaning/disinfecting IV catheter hubs, to the extent possible.

2. **"Split septum valve is preferred" (line 1078)**. There are several important issues that need to be considered here.

   First, is the term "valve" being used interchangeably with "connector"? Please be aware that the majority of connectors marketed in the USA today are all leur activated devices of some type. Are you using "valve" to mean a leur activated device (LAD)? This is important because

not all split septum connectors are LADS; at least two have straight fluid pathways (the oldest configuration of the fluid pathway). If the recommendation reads, as it does now, split septum valve, does that imply a split septum connector in the LAD category? Or only excluding LADs? And what about devices that utilize an internal rather than external septum? Is there a preference? When you discuss connectors, it is essential to be precise in the types of products you are describing, because there are so many on the market (and they change regularly!) plus today *many of them have overlapping design features.*

Note: On line 1100 the guideline mentions the use of a capped LAD. Please be aware that there are very few of these devices left, less than 1% total US connectors used. Newer and emerging products have abandoned the capped design.

Suggestion

A. Define terms precisely. While physician researchers tend to use the term "valve" the better term is "leur activated device" which is technically more accurate.
B. Align any recommendations with better defined terminology.

Second, the statement that "split septum valve is preferred" is too strong. The evidence, whether it is exists in peer reviewed journals or at lower levels in posters, abstracts etc. clearly indicates the *possibility* of an *association*, not a proven relationship, between the variables of connectors and BSI. None of the cited studies controlled for all variables and the problem of little/no access surface disinfection remains a serious confounder in these and almost all previous studies. In fact, if you examine ALL of the evidence – most of which is not in peer reviewed journals – you will see that there is as much data refuting the association as there is "proving" it. (And as the CDC's new paper on *Updating Guideline Methodology of HICPAC* notes " . . .the evidence arises from basic science studies whose strength of evidence may not be accurately reflected in the current approaches to grading evidence. This last point is particularly relevant to the evidence addressing infection prevention and control questions," p. 20-21)

Third, the issue of what is a split septum product must also be considered here, as devices today may have a septum externally or internally. In fact the designs of these products are now so complex and sophisticated that categorizing them as either "split septum" or "valve" is really inaccurate and obsolete: you can easily identify products of either type that include features from the other. The distinction between "split septum" and "valve" was probably acceptable some years ago, but today is a gross oversimplification of the products on the market. (Refer to comments under # 1 above. If a "valve" = a "leur activated device" (LAD) and there are LAD designs that incorporate a septum, then are those devices preferred – or not?)

Suggestion

A. Change the preference of split septum to valve as "unresolved" since the majority of evidence exists in posters and abstracts, rather than full text peer reviewed articles, and at least contradicts many of the conclusions in the very limited number of articles that have been published.
B. Or "soften" wording of the recommendation to read "*may* be preferred" to reflect that this is by no means scientifically proven.

3. "Positive Pressure" (lines 1105 -1107). There is no such thing. The connectors may offer

positive *displacement*, and only upon syringe disconnection, but not continuous pressure. A negative displacement connector, if the extension tubing is not clamped, will allow retrograde flow. This does not happen with a positive displacement device.

Suggestion

A. Correct misuse of the term "pressure" and replace correctly with "displacement."
B. Correct potential for backflow as described above.

4. "A silver coated connector" (line 1126-1127). There are now multiple manufacturers that have silver coated connectors cleared by the FDA and/or commercially available.

Suggestion

A. Amend sentence to indicate the availability of multiple products.

Throughout this section, the guideline refers to first and second generation products. I submit that this classification system is an over simplification. For example, most industry experts and clinical nurse specialists in vascular access will tell you that first generation connectors were split septum, negative displacement. Second gen was the LAD with negative displacement. Third gen products then began to feature first positive displacement LADS and later neutral displacement. The current, fourth gen, products are any of the above with an antimicrobial coating. And fifth gen is currently under development. You may encounter some individuals who refine the evolutions of these products to even more specific groupings.

I hope that you find these suggestions useful as you conclude your work. Thank you for the opportunity to comment on this important guideline.

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